AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE OF PAGES
	1 2

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. *(If applicable)*
002	See Block 16C	See Schedule	

6. ISSUED BY	CODE	7. ADMINISTERED BY *(If other than Item 6)*	CODE
CPOD	CPOD		

CPOD
US Environmental Protection Agency
26 West Martin Luther King Drive
Mail Code: NWD
Cincinnati OH 45268

8. NAME AND ADDRESS OF CONTRACTOR *(No., street, county, State and ZIP Code)*

R T I International
PO BOX 12194
RESEARCH TRIANGLE PARK NC 277092194

CODE (b)(4) FACILITY CODE

(x) 9A. AMENDMENT OF SOLICITATION NO.

9B. DATED *(SEE ITEM 11)*

x 10A. MODIFICATION OF CONTRACT/ORDER NO.
EP-C-11-036
0008

10B. DATED *(SEE ITEM 13)*
07/26/2012

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers ☐ is extended, ☐ is not extended.
Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA *(If required)*
See Schedule

Net Decrease: -$300,171.84

13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

CHECK ONE	
	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: *(Specify authority)* THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES *(such as changes in paying office, appropriation date, etc.)* SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
X	D. OTHER *(Specify type of modification and authority)* Mutual Agreement between the Parties and Limitation of Funds Notice

E. IMPORTANT: Contractor ☐ is not, ☒ is required to sign this document and return 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION *(Organized by UCF section headings, including solicitation/contract subject matter where feasible.)*

DUNS Number: (b)(4)

The purposes of this modification are to: de-obligate funding that is no longer needed; revise the task order cost ceiling; and to close the task order. All requirements under this task order have been delivered and accepted. The contractor may submit a Final invoice pending establishment of final indirect rates at a later date.

TOPO: William Barrett

LIST OF CHANGES:

Reason for Modification : De-obligate Funding

Total Amount for this Modification: -$300,171.84

Continued ...

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER *(Type or print)*		16A. NAME AND TITLE OF CONTRACTING OFFICER *(Type or print)*	
		Camille W. Davis	
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. Camille W. Davis ELECTRONIC SIGNATURE	16C. DATE SIGNED 07/08/2014
(Signature of person authorized to sign)			

NAME OF OFFEROR OR CONTRACTOR
R T I International

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	New Total Amount for this Version: $223,389.16 CHANGES FOR LINE ITEM NUMBER: 1 Total Amount changed From: $523,561.00 To: $223,389.16 CHANGES FOR ACCOUNTING CODE: 12-T-72DP-303DD2-2505-HQ00BM00-1272DP5009-001 Amount changed from $399,405.00 to $99,233.16 The Incremental Funding Break-out for this line of accounting is hereby revised as follows: Cost: $99,233.16 Fee: $ 0.00 Total: $99,233.16 The total Task Order break-out amounts are hereby revised as follows: Cost: $223,389.16 Fee: $ 0.00 Total: $ 223,389.16 Delivery Location Code: NRMRL CINCINNATI NRMRL CINCINNATI US Environmental Protection Agency National Risk Mgmt Research Lab 26 West Martin Luther King Drive Cincinnati OH 45268 USA Payment: RTP Finance Center US Environmental Protection Agency RTP-Finance Center (D143-02) 109 TW Alexander Drive Durham NC 27711 FOB: Destination Period of Performance: 07/30/2012 to 09/30/2013				

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE OF PAGES
	1 | 6

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. *(If applicable)*
001	09/07/2012	PR-ORD-12-02480	

6. ISSUED BY CODE CPOD

CPOD
US Environmental Protection Agency
26 West Martin Luther King Drive
Mail Code: NWD
Cincinnati OH 45268

7. ADMINISTERED BY *(If other than Item 6)* CODE CPOD

CPOD
US Environmental Protection Agency
26 West Martin Luther King Drive
Mail Code: NWD
Cincinnati OH 45268

8. NAME AND ADDRESS OF CONTRACTOR *(No., street, county, State and ZIP Code)*

RESEARCH TRIANGLE INSTITUTE
PO BOX 12194
RESEARCH TRIANGLE PARK NC 277092194

CODE (b)(4) FACILITY CODE

(x) 9A. AMENDMENT OF SOLICITATION NO.

9B. DATED *(SEE ITEM 11)*

x 10A. MODIFICATION OF CONTRACT/ORDER NO. EP-C-11-036 0008

10B. DATED *(SEE ITEM 13)* 07/26/2012

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers ☐ is extended, ☐ is not extended.
Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA *(If required)* Net Increase: $124,156.00
See Schedule

13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

CHECK ONE	
	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: *(Specify authority)* THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES *(such as changes in paying office, appropriation date, etc.)* SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
X	D. OTHER *(Specify type of modification and authority)* Mutual Agreement between the Parties

E. IMPORTANT: Contractor ☒ is not, ☐ is required to sign this document and return 0 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION *(Organized by UCF section headings, including solicitation/contract subject matter where feasible.)*

DUNS Number: (b)(4)
Comparison of Asbestos Analytical Methods
TOPO: William Barrett
LIST OF CHANGES:
Reason for Modification : Additional Work

Period Of Performance End Date changed from 29-Jul-13 to 30-Sep-13
Total Amount for this Modification: $124,156.00
New Total Amount for this Award: $523,561.00
New Total Obligated Amount for this Award: $523,561.00

Continued ...

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER *(Type or print)*		16A. NAME AND TITLE OF CONTRACTING OFFICER *(Type or print)* Camille W. Davis	
15B. CONTRACTOR/OFFEROR _____ *(Signature of person authorized to sign)*	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA Camille W. Davis *(Signature of Contracting Officer)*	16C. DATE SIGNED 09/07/2012

NSN 7540-01-152-8070
Previous edition unusable

STANDARD FORM 30 (REV. 10-83)
Prescribed by GSA
FAR (48 CFR) 53.243

NAME OF OFFEROR OR CONTRACTOR
RESEARCH TRIANGLE INSTITUTE

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	CHANGES FOR LINE ITEM NUMBER: 1 Total Amount changed From $399,405.00 To $523,561.00 Obligated Amount for this modification: $124,156.00 End Date changed from 29-Jul-13 to 30-Sep-13 NEW ACCOUNTING CODE ADDED: Account code: 12-T-72DP-303DD2-2505-HQ00BM00-1272DP5020-001 Beginning FiscalYear 12 Ending Fiscal Year Fund (Appropriation) T Budget Organization 72DP Quantity: 0 Amount: $124,156.00 Payment: RTP Finance Center US Environmental Protection Agency RTP-Finance Center (D143-02) 109 TW Alexander Drive Durham NC 27711 FOB: Destination Period of Performance: 07/30/2012 to 09/30/2013 Cost: $(b)(4) Fee: $ TOTAL $523,561.00				

PERFORMANCE WORK STATEMENT
STREAMS II
Task Order 0008, RTI EP-C-11-036
Modification 1

TITLE: Development and Comparison of Asbestos Analytical Methods

Task Order Manager (TOM)	**Alternate Task Order Manager (ATOM)**
Name: William M. Barrett	Name: David Meyer
Office: ORD/NRMRL/STD	Office: ORD/NRMRL/STD
26 W. Martin Luther King Drive	26 W. Martin Luther King Drive
Cincinnati, OH 45268	Cincinnati, OH 45268
Phone: (513) 569-7220	Phone: (513) 541-7194
Fax: (513) 569-7111	Fax: (513) 541-7111
Email: Barrett.Williamm@epa.gov	Email: Meyer.David@epa.gov

PERIOD OF PERFORMANCE: June 30, 2012 through September 30, 2013

BACKGROUND:

The following information is added to the Background section of Task Order 8 with regard to the addition of Task #5:

Current airborne asbestos analytical methods involve the collection of airborne particulate matter on a mixed cellulose ester (MCE) membrane filter. The MCE filter is then analyzed for asbestos using either optical or electron microscopic methods. The microscopic methods are labor intensive and, therefore, expensive as the microscopist must manually search the prepared filter sample for asbestos fibers. The method detection limits are based upon the area of the filter counted. In order to reduce the detection limit by half, twice the area of the filter must be examined and counted. While the method can be improved by increasing the area of the filter examined by the microscopist, minimal gains in improving the detection limit require substantially increasing analytical costs.

The use of image processing technology has been demonstrated for a variety of microscopic analyses. For example, the National Institutes of Health (NIH) has developed ImageJ (http://rsb.info.nih.gov/ij/), an image processing software package that has microscopic image analysis macros used in various cell counting analyses. Specific asbestos automated counting applications include the Clemex Vision PE system (http://clemex.com/en/Products/Multipurpose-Image-Analysis/Clemex-Vision-PE/Description), which can be used for phase contrast microscopy. Additionally, Zamengo, et al (2009) documents the use of image processing for scanning electron microscopic analysis.[1] However, none of these systems have

[1] L. Zamengo, N. Barbiero, M. Gregio, G. Orrù, Combined scanning electron microscopy and image analysis to investigate airborne submicron particles: A comparison between personal samplers, Chemosphere, Volume 76, Issue 3, July 2009, Pages 313-323.

been developed or tested for use with transmission electron microscopic (TEM) methods, the primary method used by the USEPA.

The tasks added by this modification (Modification 1) will involve conducting a review of the state of the art of automated counting and the preparation of a report documenting the state of the art pertaining to image processing software related to an automated counting system for use with the counting rules identified in Appendix C of the International Organization for Standardization's Ambient Air – Determination of asbestos fibers – Direct transfer transmission electron microscope method (ISO 10312). The report will further document the algorithms that can be implemented to conduct the image analysis and other requirements of the automated counting system.

Task 1: Preparation of the Quality Assurance Project Plan and Health and Safety Plan

The following paragraph is added to Task 1 under Modification 1:
This is an applied research/technology evaluation project subject to NRMRL *Category 3* Quality Assurance requirements. Attached is a copy of the current approved quality assurance project plan (QAPP), entitled, "Comparison of Asbestos Analytical Methods," project tracking number S-15179-QP-1-4.

Task 2: Preparation of Asbestos-Loaded Filters
There is no change to Task 2 under Modification 1.

Task 3: Sample Analysis
There is no change to Task 3 under Modification 1.

Task 4: Reporting

The following paragraph is added to Task 4: Reporting:

The contractor shall prepare a draft report documenting the results of the literature review for EPA review and comment for work performed under Task 8, Development of an Algorithm for the Image Analysis Software. Based upon EPA comments, the contractor shall prepare a final report of the results of the literature review.

Task 5 is added to Task Order 8 as follows:

Task 5: Development of an Algorithm for the Image Analysis Software

The contractor shall conduct a review of image analysis literature and a survey of available image processing software to identify potential methods for implementation of an automated counting system for asbestos fibers in accordance with ISO 10312 Appendix C counting rules. This review may include, as needed, testing of existing software packages and/or development of proof of concept packages. The contractor will prepare a literature review report that documents the results of the literature search and market survey. This report shall also document a computer algorithm that can be implemented to conduct the image analysis for the development of the

automated counting system. The algorithm shall include the steps needed to identify an asbestos fiber on a TEM image

Schedule

Task 1 – There is no change to the Delivery Schedule for Task 1 under Modification 1.

Task 2 – There is no change to the Delivery Schedule for Task 2 under Modification 1.

Task 3 – There is no change to the Delivery Schedule for Task 3 under Modification 1.

Task 4 – There is no change to the Delivery Schedule for Task 4 under Modification 1.

The following is added to the Delivery Schedule:
Task 5 – Report preparation schedule for Task 5 shall be as follows:

- Prepare the draft report within 270 days after Modification 1 approval.
- EPA shall review the report within 30 days after receipt of draft report

Appendix A: There is no change to Appendix A under Modification 1.

SURVEILLANCE PLAN
Task Order 0008, RTI EP-C-11-036
Modification 1

Development and Comparison of Asbestos Analytical Methods

Performance Objective (Task)	Performance Standard (PS)	Surveillance Plan (SP)	Contractor Incentive (CI)	✓ or X
Task 1: Prepare Quality Assurance Project Plan	Contractor prepares QAPP for project within 60 days of award.	TOM will ensure that the Quality Assurance Manager approves QAPP prior to the start of any work.	TOM will address compliance in PPE	✓
Task 2: Preparation of Test Samples.	Contractor successfully prepares a set of samples under laboratory conditions for analysis by the various analytical methods being compared.	TOM will verify high quality sample preparation.	TOM will address compliance in PPE	✓
Task 3: Sample Analysis.	Contractor will provide laboratory sample analytical reports as required by the analytical methods investigated.	TOM will document whether receipt of deliverable is timely. TOM will document whether quality of deliverable is at an acceptable level.	TOM will address compliance in PPE	✓
Task 4: Reporting.	Contractor provides full and complete documentation of the results of all sample preparation and testing 120 days after sample analysis has been completed and literature search and market survey.	TOM will document whether receipt of deliverable is timely. TOM will document whether quality of deliverable is at an acceptable level.	TOM will address compliance in PPE	✓
Task 5: Development of an Algorithm for the Image Analysis Software	Contractor conducts literature search and market survey within 270 days after award.	TOM will review literature review and market survey status with contractor on a monthly basis.	TOM will address compliance in PPE	✓

AWARD/CONTRACT	1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)	RATING	PAGE OF PAGES 1 | 22

2. CONTRACT (Proc. Inst. Ident.) NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQUEST/PROJECT NO.
EP-C-11-036/0008	See Block 20C	PR-ORD-12-01111

5. ISSUED BY	CODE	6. ADMINISTERED BY (If other than Item 5)	CODE
CPOD	CPOD	CPOD	CPOD
US Environmental Protection Agency		US Environmental Protection Agency	
26 West Martin Luther King Drive		26 West Martin Luther King Drive	
Mail Code: NWD		Mail Code: NWD	
Cincinnati OH 45268		Cincinnati OH 45268	

7. NAME AND ADDRESS OF CONTRACTOR (No., Street, City, Country, State and ZIP Code)	8. DELIVERY	9. DISCOUNT FOR PROMPT PAYMENT
RESEARCH TRIANGLE INSTITUTE PO BOX 12194 RESEARCH TRIANGLE PARK NC 277092194	☐ FOB ORIGIN ☒ OTHER (See below)	

10. SUBMIT INVOICES (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN	ITEM

CODE	(b)(4)	FACILITY CODE

11. SHIP TO/MARK FOR	CODE	12. PAYMENT WILL BE MADE BY	CODE
NRMRL CINCINNATI	NRMRL CINCINNATI	RTP Finance Center	RTP FMC
US Environmental Protection Agency		US Environmental Protection Agency	
National Risk Mgmt Research Lab		RTP-Finance Center (D143-02)	
26 West Martin Luther King Drive		109 TW Alexander Drive	
Cincinnati OH 45268		Durham NC 27711	

13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION:	14. ACCOUNTING AND APPROPRIATION DATA
☐ 10 U.S.C. 2304 (c) ( ) ☐ 41 U.S.C. 253 (c) ( )	See Schedule

15A. ITEM NO	15B. SUPPLIES/SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT
	Continued				
	15G. TOTAL AMOUNT OF CONTRACT ▶				$399,405.00

16. TABLE OF CONTENTS

(X)	SEC.	DESCRIPTION	PAGE(S)	(X)	SEC.	DESCRIPTION	PAGE(S)
		PART I - THE SCHEDULE				PART II - CONTRACT CLAUSES	
	A	SOLICITATION/CONTRACT FORM			I	CONTRACT CLAUSES	
	B	SUPPLIES OR SERVICES AND PRICES/COSTS				PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACH.	
	C	DESCRIPTION/SPECS./WORK STATEMENT			J	LIST OF ATTACHMENTS	
	D	PACKAGING AND MARKING				PART IV - REPRESENTATIONS AND INSTRUCTIONS	
	E	INSPECTION AND ACCEPTANCE			K	REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS	
	F	DELIVERIES OR PERFORMANCE					
	G	CONTRACT ADMINISTRATION DATA			L	INSTRS., CONDS., AND NOTICES TO OFFERORS	
	H	SPECIAL CONTRACT REQUIREMENTS			M	EVALUATION FACTORS FOR AWARD	

CONTRACTING OFFICER WILL COMPLETE ITEM 17 (SEALED-BID OR NEGOTIATED PROCUREMENT) OR 18 (SEALED-BID PROCUREMENT) AS APPLICABLE

17. ☐ CONTRACTOR' S NEGOTIATED AGREEMENT (*Contractor is required to sign this document and return* _____ *copies to issuing office.*) Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. *(Attachments are listed herein.)*

18. ☒ SEALED-BID AWARD (*Contractor is not required to sign this document.*) Your bid on Solicitation Number _____, including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the items listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your bid, and (b) this award/contract. No further contractual document is necessary. (Block 18 should be checked only when awarding a sealed-bid contract.)

19A. NAME AND TITLE OF SIGNER (Type or print)	20A. NAME OF CONTRACTING OFFICER
	Matthew Growney

19B. NAME OF CONTRACTOR	19C. DATE SIGNED	20B. UNITED STATES OF AMERICA	20C. DATE SIGNED
BY _____		BY _____	
(Signature of person authorized to sign)		*(Signature of the Contracting Officer)*	

NAME OF OFFEROR OR CONTRACTOR

RESEARCH TRIANGLE INSTITUTE

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	DUNS Number: (b)(4) Comparison of Asbestos Analytical Methods TOPO: William Barrett Accounting Info: 12-T-72DP-303DD2-2505-HQ00BM00-1272DP5009-001 BFY: 12 Fund: T Budget Org: 72DP Program (PRC): 303DD2 Budget (BOC): 2505 Job #: HQ00BM00 DCN - Line ID: 1272DP5009-001 FOB: Destination Period of Performance: 07/30/2012 to 07/29/2013				
0001	Comparison of Asbestos Analytical Methods				399,405.00
	The obligated amount of award: $399,405.00. The total for this award is shown in box 15G.				

ATTACHMENT #1
TO THE STATEMENT OF WORK

NRMRL QA Requirements and Definitions

EPA's Quality System Website: http://www.epa.gov/quality/

EPA's Requirements and Guidance Documents: http://www.epa.gov/quality/qa_docs.html

In accordance with EPA Order 5360.1 A2, conformance to ANSI/ASQC E4 must be demonstrated by submitting the quality documentation described herein. All quality documentation shall be submitted to the Government for review. The Government will review and return the quality documentation, with comments, and indicate approval or disapproval. If the quality documentation is not approved, it must be revised to address all comments and shall be resubmitted to the Government for approval. Work involving environmental data collection, generation, use, or reporting shall not commence until the Government has approved the quality documentation. The QAPP shall be submitted to the Government at least thirty (30) days prior to the beginning of any environmental data gathering or generation activity in order to allow sufficient time for review and revisions to be completed. After the Government has approved the quality documentation, the Contractor shall also implement it as written and approved by the Government.

Definitions:

Environmental Data - These are any measurements or information that describe environmental processes, location, or conditions; ecological or health effects and consequences; or the performance of environmental technology. For EPA, environmental data include information collected directly from measurements, produced from software and models, and compiled from other sources such as data bases or the literature.

Quality Assurance (QA) - Quality assurance is a system of management activities to ensure that a process, item, or service is of the type and quality needed by the customer. It deals with setting policy and running an administrative system of management controls that cover planning, implementation, and review of data collection activities and the use of data in decision making. Quality assurance is just one part of a quality system.

Quality Assurance Project Plan (QAPP) - A QAPP is a document that describes the necessary quality assurance, quality control, and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria. A QAPP documents project-specific information.

Quality Control (QC) - Quality control is a technical function that includes all the scientific precautions, such as calibrations and duplications, that are needed to acquire data of known and adequate quality.

Quality Management Plan (QMP) - A QMP is a document that describes an organization's/program's quality system in terms of the organizational structure, policy and procedures, functional responsibilities of management and staff, lines of authority, and required interfaces for those planning, implementing, documenting, and assessing all activities conducted. A QMP documents the overall organization/program, and is primarily applicable to multi-year, multi-project efforts. An organization's/program's QMP shall address all elements listed in the "Requirements for Quality Management Plans" in Appendix B of the NRMRL QMP.

Quality System - A quality system is the means by which an organization manages its quality aspects in a systematic, organized manner and provides a framework for planning, implementing, and assessing work performed by an organization and for carrying out required quality assurance and quality control activities.

R-2 - EPA Requirements for Quality Management Plans (EPA/240/B-01/002) March, 2001, http://www.epa.gov/quality/qs-docs/r2-final.pdf

R-5 - EPA Requirements for QA Project Plans (EPA/240/B-01/003) March, 2001 http://www.epa.gov/quality/qs-docs/r5-final.pdf

Substantive Change - Substantive change is any change in an activity that may alter the quality of data being used, generated, or gathered.

____ **NRMRL's Quality System Specifications:**

(1) a description of the organization's Quality System (QS) and information regarding how this QS is documented, communicated and implemented;

(2) an organizational chart showing the position of the QA function;

(3) delineation of the authority and responsibilities of the QA function;

(4) the background and experience of the QA personnel who will be assigned to the project; and

(5) the organization's general approach for accomplishing the QA specifications in the SOW.

Category Level Designations (determines the level of QA required):

____ **Category I Project** - applicable to studies performed to generate data used for enforcement activities, litigation, or research project involving human subjects. The QAPP shall address all elements listed in R-5.

____ **Category II Project** - applicable to studies performed to generate data used in support of the development of environmental regulations or standards. The QAPP shall address all elements listed in R-5.

__X__ **Category III Project** - applicable to projects involving applied research or technology evaluations. The QAPP shall address the applicable sections of R-5, as outlined in the NRMRL QAPP requirements for the specific project type (see below).

____ **Category IV Project** - applicable to projects involving basic research or preliminary data gathering activities. The QAPP shall address the applicable sections of R-5, as outlined in the NRMRL QAPP requirements for the specific project type (see below).

Guidance for QAPPs by Project Type (described in more detail on subsequent pages):

These outlines of NRMRL QAPP Requirements for various project types, from Appendix B of the NRMRL QMP (except where otherwise noted), are condensed from typically applicable sections of R-5 (EPA Requirements for QA Project Plans) and are intended to serve as a starting point when preparing a QAPP. These lists and their format may not fit every research scenario, and QAPPs must conform to applicable sections of R-5 in a way that fully describes the research plan and appropriate QA and QC measures to ensure that the data are of adequate quality and quantity to fit their intended purpose.

__X__ **Applied Research Project** - pertains to a study performed to generate data to demonstrate the performance of accepted processes or technologies under defined conditions. These studies are often pilot- or field-scale. Additional guidance is given in "QAPP Requirements for Applied Research Projects" (attached).

____ **Basic Research Project** - pertains to a study performed to generate data used to evaluate unproven theories, processes, or technologies. These studies are often bench-scale. Additional guidance is given in "QAPP Requirements for Basic Research Projects".

____ **Design, Construction, and/or Operation of Environmental Technology Project** - pertains to engineering projects involving environmental technologies, an all inclusive term used to describe pollution control devices and systems, waste treatment processes and storage facilities, and site remediation technologies and their components that may be utilized to remove pollutants or contaminants from or prevent them from entering the environment. Comprehensive guidance can be found in the EPA Quality System document "Guidance on Quality Assurance for Environmental Technology Design, Construction, and Operation" G-11, at http://www.epa.gov/quality/qs-docs/g11-final-05.pdf.

____ **Method Development Project** - pertains to situations where there is no existing standard method, or a standard method needs to be significantly modified for a specific application. Additional guidance is given in "QAPP Requirements for Method Development Projects"
.

____ **Model Development Project** - includes all types of mathematical models including static, dynamic, deterministic, stochastic, mechanistic, empirical, etc. Comprehensive guidance is provided in the EPA Quality System document "Guidance for Quality Assurance Project Plans for Modeling" G-5M, http://www.epa.gov/quality/qs-docs/g5m-final.pdf. Abbreviated guidance is provided in "QAPP Requirements for Research Model Development and Application Projects" (attached).

_X_ **Sampling and Analysis Project** - pertains to the collection and analysis of samples with no objectives other than to provide characterization or monitoring information. Additional guidance is given in "QAPP Requirements for Sampling and Analysis Projects".

____ **Secondary Data Project** - pertains to environmental data collected from other sources, by or for EPA, that are used for purposes other than those originally intended. Sources may include: literature, industry surveys, compilations from computerized databases and information systems, and computerized or mathematical models of environmental processes. Additional guidance is given in "QAPP Requirements for Secondary Data Projects".

____ **Software Development Project** - pertains to projects dealing with software development or data management and includes all types of software/hardware systems development, data base design and maintenance, and data validation and verification systems. Additional guidance is given in "QAPP Requirements for Software and Data Management Projects".

QAPP REQUIREMENTS FOR APPLIED RESEARCH PROJECTS

An applied research project is a study to demonstrate the performance of technologies under defined conditions. These studies are often pilot- or field-scale. The following requirements should be addressed as applicable.

SECTION 0.0, DISTRIBUTION LIST

A distribution list shall be provided to facilitate the distribution of the most recent current version of the QAPP to all the principal project participants.

SECTION 1.0, PROJECT DESCRIPTION AND OBJECTIVES

1.1 The purpose of study shall be clearly stated.

1.2 The process, site, facility, and/or environmental system to be tested shall be described.

1.3 Project objectives shall be clearly stated and identified as primary or non-primary.

SECTION 2.0, PROJECT ORGANIZATION

2.1 Key points of contact for each organization involved in the project shall be identified.

2.2 All QA Managers and their relationship in the organizations (*i.e.*, location within each organization) shall be identified with evidence that the QA Manager is independent of project management.

2.3 Responsibilities of all other project participants and their relationship to other project participants shall be identified, meaning that organizations responsible for planning, coordination, sample collection, sample custody, measurements (*i.e.*, analytical, physical, and process), data reduction, data validation, and report preparation shall be clearly identified.

SECTION 3.0, EXPERIMENTAL APPROACH

3.1 The general approach and the test conditions for each experimental phase shall be provided. The statistical methods that will be used to evaluate the data (*i.e.*, ANOVA, or summary statistics) should be identified.

(NOTE: As deemed appropriate to the project by the TLP, the information requested in Sections 3.2, 3.3, and 3.4 may be presented here or in Section 4; the information requested

in Sections 3.5 may be presented here or in Section 5; and the information requested in Sections 3.6 may be presented here or in Section 7.)

3.2 The sampling strategy shall be included and evidence must be presented to demonstrate that the strategy is appropriate for meeting primary project objectives, *i.e.*, a description of the statistical method or scientific rationale used to select sample sites and number of samples shall be provided.

3.3 Sampling/monitoring points for all measurements (*i.e.*, including locations and access points) shall be identified.

3.4 The frequency of sampling/monitoring events, as well as the numbers for each sample type and/or location shall be provided, including QC and reserve samples.

3.5 All measurements (*i.e.*, analytical [chemical, microbiological, assays], physical, and process) shall be identified for each sample type or process, and project-specific target analytes shall be listed and classified as critical or noncritical in the QAPP.

3.6 The planned approach (statistical and/or non-statistical) for evaluating project objectives shall be included.

SECTION 4.0, SAMPLING PROCEDURES

4.1 Whenever applicable, the method used to establish steady-state conditions shall be described.

4.2 Known site-specific factors that may affect sampling/monitoring procedures shall be described.

4.3 Any site preparation needed prior to sampling/monitoring shall be described.

4.4 Each sampling/monitoring procedure to be used shall be discussed or referenced. If compositing or splitting samples, those procedures shall be described.

4.5 For samples requiring a split sample for either QA/QC purposes or for shipment to a different laboratory, the QAPP shall identify who is responsible for splitting samples, and where the splitting is performed (*e.g.*, field versus lab).

4.6 If sampling/monitoring equipment is used to collect critical measurement data (*i.e.*, used to calculate the final concentration of a critical parameter), the QAPP shall describe how the sampling equipment is calibrated, the frequency at which it is calibrated, and the acceptance criteria for calibration or calibration verification, as appropriate.

4.7 If sampling/monitoring equipment is used to collect critical measurement data, the QAPP shall describe how cross-contamination between samples is avoided.

4.8 The QAPP shall include a discussion of the procedures to be used to assure that representative samples are collected.

4.9 A list of sample quantities to be collected, and the sample amount required for each analysis, including QC sample analysis, shall be specified.

4.10 Containers used for sample collection, transport, and storage for each sample type shall be described.

4.11 The method for uniquely identifying each samples shall be described.

4.12 Sample preservation methods (*e.g.*, refrigeration, acidification, *etc.*), including specific reagents, equipment, and supplies required for sample preservation shall be described.

4.13 Holding time requirements shall be noted.

4.14 Procedures for packing and shipping samples shall be described.

4.15 Procedures to maintain chain-of-custody (*e.g.*, custody seals, records) during transfer from the field to the laboratory, in the laboratory, and among contractors and subcontractors shall be described to ensure that sample integrity is maintained.

4.16 Sample archival requirements for each relevant organization shall be provided.

SECTION 5.0, TESTING AND MEASUREMENT PROTOCOLS

5.1 Each measurement method to be used shall be described in detail or referenced. Modifications to EPA-approved or similarly validated methods shall be specified.

5.2 For unproven methods, verification data applicable to expected matrices shall be included in the QAPP meaning the QAPP shall provide evidence that the proposed method is capable of achieving the desired performance.

5.3 For measurements which require a calibrated system, the QAPP shall include specific calibration procedures applicable to each project target analyte, and the procedures for verifying both initial and continuing calibrations (including frequency and acceptance criteria, and corrective actions to be performed if acceptance criteria are not met).

SECTION 6.0, QA/QC CHECKS

6.1 At a minimum, the QAPP shall include quantitative acceptance criteria for QA objectives associated with accuracy, precision, detection limits, and completeness for critical measurements (process, physical, and analytical, as applicable) for each matrix.

6.2 Any additional project-specific QA objectives shall be presented, including acceptance criteria. This includes items such as mass balance requirements.

6.3 The specific procedures used to assess all identified QA objectives shall be fully described.

6.4 The QAPP shall list and define all other QC checks and/or procedures (*e.g.*, blanks, surrogates, controls, *etc.*) used for the project, both field and laboratory.

6.5 For each specified QC check or procedure, required frequencies, associated acceptance criteria, and corrective actions to be performed if acceptance criteria are not met shall be included.

SECTION 7.0, DATA REPORTING, DATA REDUCTION, AND DATA VALIDATION

7.1 The reporting requirements (*e.g.*, units, reporting method [wet or dry]) for each measurement and matrix shall be identified.

7.2 The deliverables expected from each organization responsible for field and laboratory activities shall be listed.

7.3 Data reduction procedures specific to the project, and also specific to each organization, shall be summarized.

7.4 Data validation procedures specific to each organization used to ensure the reporting of accurate project data to internal and external clients shall be summarized.

7.5 Data storage requirements for each organization shall be provided.

7.6 The product document that will be prepared for the project shall be specified (*e.g.*, journal article, final report, *etc.*). The contents of this document can be referenced to a NRMRL or program-specific QMP, if appropriate.

SECTION 8.0, ASSESSMENTS

8.1 The QAPP shall identify all scheduled audits (*i.e.*, both technical system audits [TSAs] and performance evaluations [PEs]) to be performed, who will perform these audits, and who will receive the audit reports.

8.2 The QAPP shall provide procedures that are to be followed that will ensure that necessary corrective actions will be performed.

8.3 The responsible party(-ies) for implementing corrective actions shall be identified.

SECTION 9.0, REFERENCES

References shall be provided either in the body of the text as footnotes or in a separate section.

NRMRL QAPP REQUIREMENTS FOR RESEARCH MODEL DEVELOPMENT AND APPLICATION PROJECTS

A research model project is a study performed to develop a new model or apply an existing model to provide information to support non-regulatory environmental research or decision-making. A QAPP must be submitted at the beginning of a research model development or application project. The QAPP should specify the quality requirements needed to ensure the quality of the results produced by the model. The recommended format for research model development QAPPs is presented below; guidance for completing each section is provided in italics. (For model application projects, a smaller subset of requirements needs to be addressed, as appropriate; e.g., information on code development would not be included.) If data will be generated to develop or calibrate the model, a separate QAPP is needed and should address the requirements applicable to the type of research project (e.g., basic research, applied research). If a model will be developed to support regulatory environmental decision-making, additional requirements may apply. The Division QA Manager should be consulted.

SECTION 1.0, PROJECT DESCRIPTION

1.1 Discuss the scope and purpose of the model.

Provide a brief statement of the scope and purpose. The specific problem which needs to be addressed should be discussed, including the intended users of the model.

1.2 Identify the project's objectives.

Discuss the specific objectives for this project, including the expected product and a timetable for completion.

1.3 Identify the roles and responsibilities of all project participants and support facilities.

Identify project personnel and key support facilities (including computer facilities). Discuss the duties/responsibilities for each. An organizational chart can be used to show lines of authority and communication.

SECTION 2.0, MODEL DESCRIPTION

2.1 Discuss the model parameters, including the theoretical approach for the model and the mathematical relationship between input and output variables.

Provide an overview of the model parameters, including:

- *model origin and its original purpose, if applicable*

- *parameters and variables*
- *the algorithms and equations that have been developed to support the model theory, along with the sources of the algorithms*
- *spatial extent (individual, group, population)*
- *spatial resolution (location independent/dependent, dimensionality)*
- *temporal extent (length of modeling period)*
- *temporal resolution (time step)*
- *model structure (e.g., stochastic vs deterministic, structural framework).*

2.2 Discuss any initial assumptions regarding model development/application.

Initial assumptions made during model development should be identified.

2.3 Specify required sources for model databases and any requirements for these data (e.g., quality, quantity, spatial, and temporal applicability). If data sources are not currently known, describe the criteria used to identify sources.

The purpose of assessing data quality is to evaluate, to the extent possible, the reliability of the existing data base(s). Procedures for determining precision, accuracy, representativeness, completeness, and comparability of existing data should be summarized. Specific parameters to be discussed include:

- *source of data and criteria for acceptance or rejection*
- *any modifications from existing data*
- *data format, maintenance, and archiving.*

SECTION 3.0, MODEL DEVELOPMENT

3.1 Discuss requirements for code development.

QA procedures for code development should include complete record keeping of the model development and of modifications made in the code. Required records include:

- *- assumptions*
- *parameter values and sources*
- *changes and verification of changes made in code*
- *output of model runs and interpretation*

If any modifications are made to the model coding, the code should be tested again; all QA procedures for model development should again be applied, including accurate record keeping and reporting.

The code documentation should include:

- *model specifications*
- *model description*

- *flow charts*
- *description of routines*
- *data base description*
- *source listing*
- *error messages.*

3.2 Discuss computer requirements for both hardware and software.

Identify computer requirements, including:

- *programming language (FORTRAN, BASIC, etc.) and ANSII standard*
- *model portability*
- *memory requirements*
- *required hardware/software for application*
- *data standards for information storage and retrieval (refer to Office of Environmental Information guidance - www.epa.gov/irmpoil8/polman/chaptr05.htm)*

When appropriate, a review of existing software should first be considered to determine capability for implementing the new model.

3.3 Discuss how the code will be verified.

The objective of the code verification process is to check the correctness and accuracy of the computational algorithms used to solve the governing equations and to assure that the computer code is fully operational.

The inspection of the computer code is part of the model review process. In this inspection, attention is given to the manner in which modern programming principles have been applied with respect to code structure, compliance with programming standards, efficient use of programming languages, and internal documentation. This step may reveal programming or logic errors that are difficult or impossible to detect in verification runs.

3.4 Describe the requirements for model documentation.

Model documentation is defined as the information recorded during the design, development, and maintenance of the model, in order to explain pertinent aspects, including purposes, methods, logic, relationships, capabilities, and limitations. It is the principle instrument of communication used by the model author, the model user, and the system operator.

Good documentation includes a description of (some of these may have been discussed previously):

- *the equations on which the model is based*
- *the underlying assumptions*

- *the boundary conditions that can be incorporated in the model*
- *the method used to solve the equations*
- *limiting conditions*

The documentation may also include:

- *user's guide (electronic or paper)*
- *source code*
- *instructions for preparing data files*
- *example problems complete with input and output*
- *programmer's instructions*
- *computer operator's instructions*
- *a report of the initial code verification*
- *documentation of significant changes to the model*
- *procedures for maintenance and user support, if applicable.*

SECTION 4.0, MODEL CALIBRATION

Model calibration is defined as the process of refining the model to achieve a desired degree of correspondence between the model output and actual observations of the environmental system that the model is intended to represent. Model development is an evolutionary process responding to new research results, developments in technology, and changes in user requirements. Model calibration needs to follow this dynamic process and should be applied each time the model is modified.

4.1 Discuss how the model will be calibrated.

Identify the type and source of data (e.g., new data, existing data, professional judgement, expert opinion elicitation) that will be used to calibrate the model. If data sources are not currently known, describe the criteria used to identify sources.

4.2 Describe any requirements for the data that will be used to calibrate the model.

Calibration data requirements with respect to quality, quantity, and spatial and temporal applicability should be specified, as applicable.

4.3 Specify criteria which need to be met for the difference between predicted and observed data during model calibration.

The acceptance criteria which need to be met for the difference between predicted and observed data should be specified. The statistical methods to be used (e.g., "goodness-of-fit," regression analyses) should also be discussed. If criteria cannot be specified, this should be discussed.

SECTION 5.0, MODEL ASSESSMENT (VALIDATION) AND APPLICATION

5.1 Discuss the assessments planned to ensure the acceptability of model outputs.

This element of the QAPP documents the types of assessments to be performed throughout the various stages of model development and application, the purpose of each assessment and the specific model features that each assessment is to address, and the expected periods of time in which the assessments will take place. Details regarding how the assessments will be performed and by whom need to be provided. The specific assessments are based on a clear understanding and statement of the purpose of the model and the accuracy of the model outputs needed (predictions).

In general, this QA Project Plan element specifies the following types of information:

- *a description of the assessment/oversight strategies and schedule of assessment activities, including the order in which the assessments will be conducted and how the total set of assessments is structured to provide a complete and comprehensive oversight;*
- *a description of how each assessment will be planned and conducted;*
- *the organizations and individuals that are expected to participate in assessments, including peer reviews;*
- *the information expected, success criteria, and documentation for each assessment.*

Additional guidance on assessments is provided in EPA QA/G-5M (www.epa.gov/quality/qa_docs.html).

5.2 Identify any restrictions on the use of the model.

Restrictions on model application should be outlined. Categories of restrictions include:

- *assumptions*
- *parameter values and sources*
- *boundary and initial conditions*
- *validation/calibration of the model*
- *output and interpretation of model runs*

If any of these items has been presented and discussed previously, inclusion here is not necessary.

SECTION 6.0, REFERENCES

Provide references to methods and applicable publications.

REFERENCES

EPA, Environmental Research Laboratory. Quality Assurance Guidelines for Modeling Development and Application Projects, November 1991.

EPA QA/G-5M. 2002. Guidance for Quality Assurance Project Plans for Modeling.

van der Heijde, P.K.M. 1989. Quality Assurance and Quality Control in Groundwater Modeling. IGWMC Groundwater Modeling Publications, Holcomb Research Institute, Butler University, Indianapolis, IN:25.